



# Sol-Gel

Advanced Topical Therapy

NASDAQ: SLGL

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# Our Dermatology Company



- Primed to become a global dedicated dermatological company by developing a combination of branded and generic topical drug products
- Expecting results during 2019 from pivotal trials of two branded pipeline candidates, based on a proprietary topical microencapsulation delivery system
- Eight established collaborations with two strategic partners on generic candidates already resulted in one approval and one tentative approval by the FDA. First generic product reached the market in February 2019
- Proven track record combined with broad dermatological knowhow

# Common Indications Requiring Better Therapies

## Acne Vulgaris

- A disease of the pilosebaceous unit, involving abnormalities in sebum production, follicular epithelial desquamation, bacterial proliferation and inflammation
- Benzoyl peroxide (BPO) and tretinoin are mainstay therapies
- Tretinoin is the most widely used Rx topical retinoid, but is rapidly decomposed by BPO and causes irritation
- BPO/tretinoin combination does not currently exist on the market
- ~\$2.7 billion sales in the U.S. in 2018 of several promoted topical brands and many generics, of which fixed-dose combination drugs account for ~\$0.9 billion
- Dermatologists often prefer branded topical drugs even though cheaper generics and OTC alternatives exist

## Papulopustular Rosacea

- A chronic, inflammatory skin condition affecting nearly 5 million people in the US
- ~\$0.4 billion sales of topical products in the U.S. in 2018 : Soolantra®, Finacea® and generic metronidazole
- Poor patient adherence to current drugs

# Our Branded Drug Product Candidates

**TWIN**

**acne vulgaris**

- **A cream containing a fixed-dose combination of encapsulated tretinoin and encapsulated benzoyl peroxide**
- Major challenges were the instability of tretinoin in the presence of benzoyl peroxide and irritation
- Encapsulation allows stabilization and is also expected to contribute to patient compliance
- Opportunity exists for shift from prescribing tretinoin and existing combinations to prescribing TWIN
- We estimate peak annual sales of \$350M - \$400M<sup>(†)</sup>.

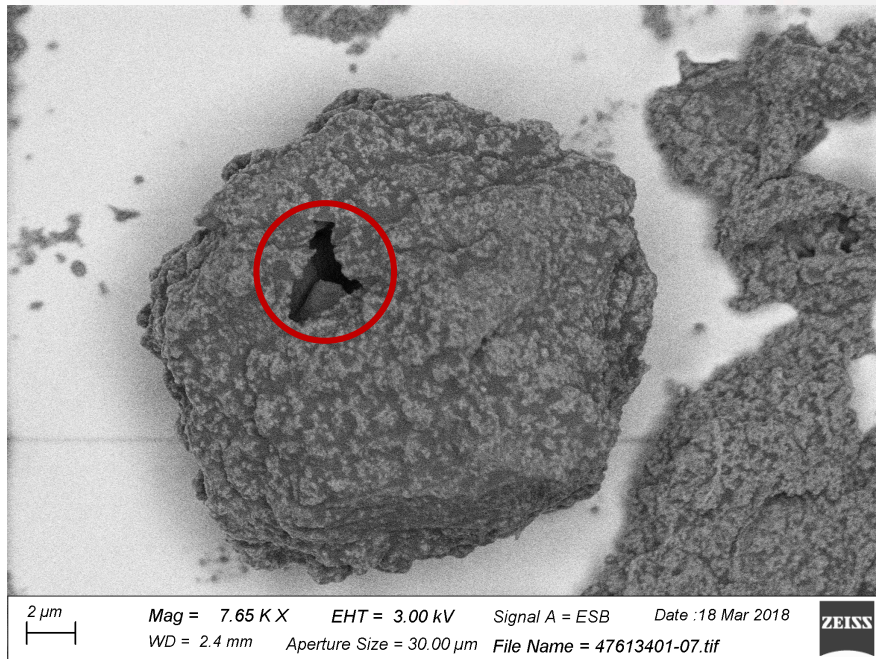
**Epsolay®**

**papulopustular  
rosacea**

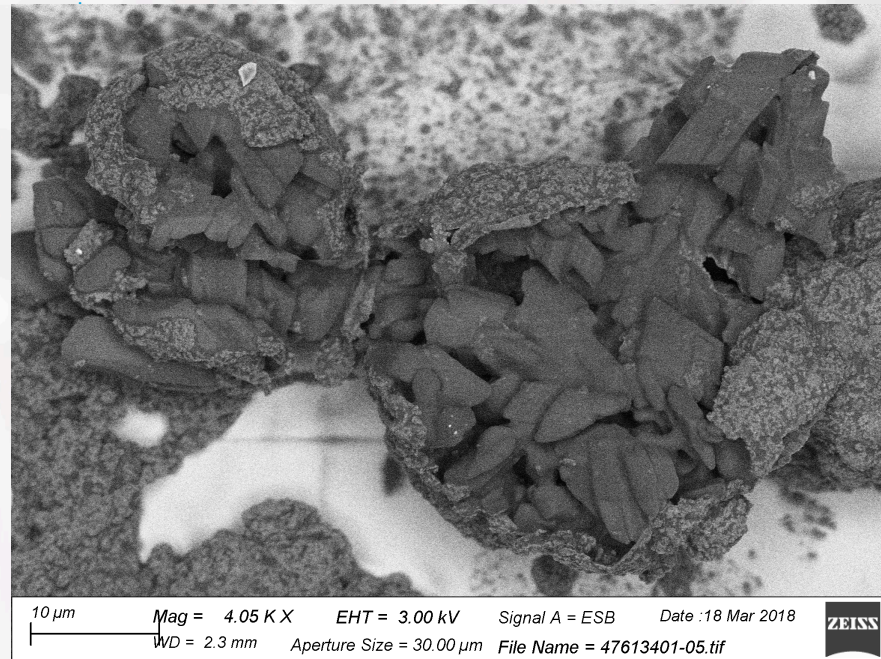
- **A cream containing encapsulated benzoyl peroxide, 5%**
- Encapsulation was designed to reduce irritation caused by benzoyl peroxide
- Potential to be the 1<sup>st</sup> FDA-approved single-active benzoyl peroxide prescription drug product
- We estimate peak annual sales of \$75M - \$100M<sup>(†)</sup>

# Our Microencapsulation Platform

Encapsulated tretinoin (E-ATRA)



Broken microcapsule containing multiple tretinoin (ATRA) crystals



SEM pictures of our silica-based encapsulated tretinoin



# Positive TWIN Factorial Phase II Results (ITT)<sup>(†)</sup>

## Success in Dichotomized IGA at Week 12

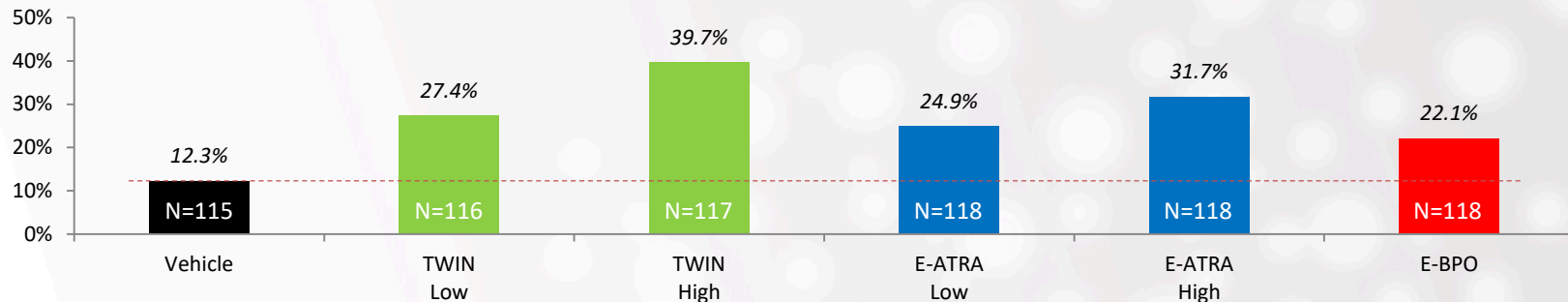
*P-value vs. vehicle*

0.006

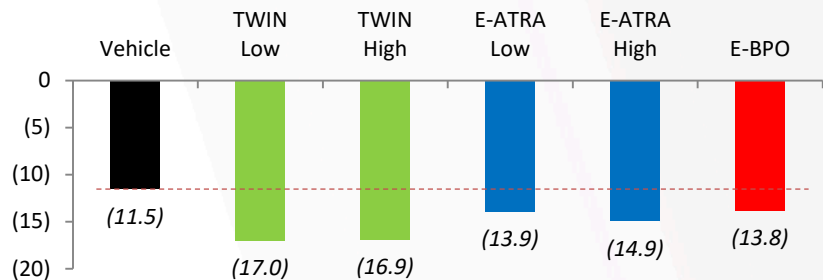
<0.001

0.015

0.001



## Inflammatory Lesion Mean Absolute Change from Baseline at Week 12



*P-value vs. vehicle*

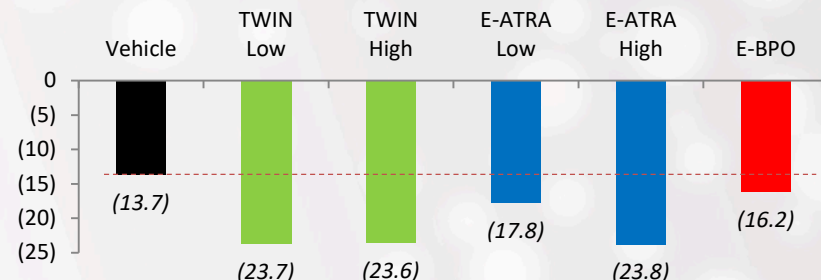
<0.001

<0.001

0.060

0.003

## Non-Inflammatory Lesion Mean Absolute Change from Baseline at Week 12



*P-value vs. vehicle*

<0.001

<0.001

0.002

<0.001

# Acne Trials Efficacy Results<sup>(†)</sup>: Moderate Patients



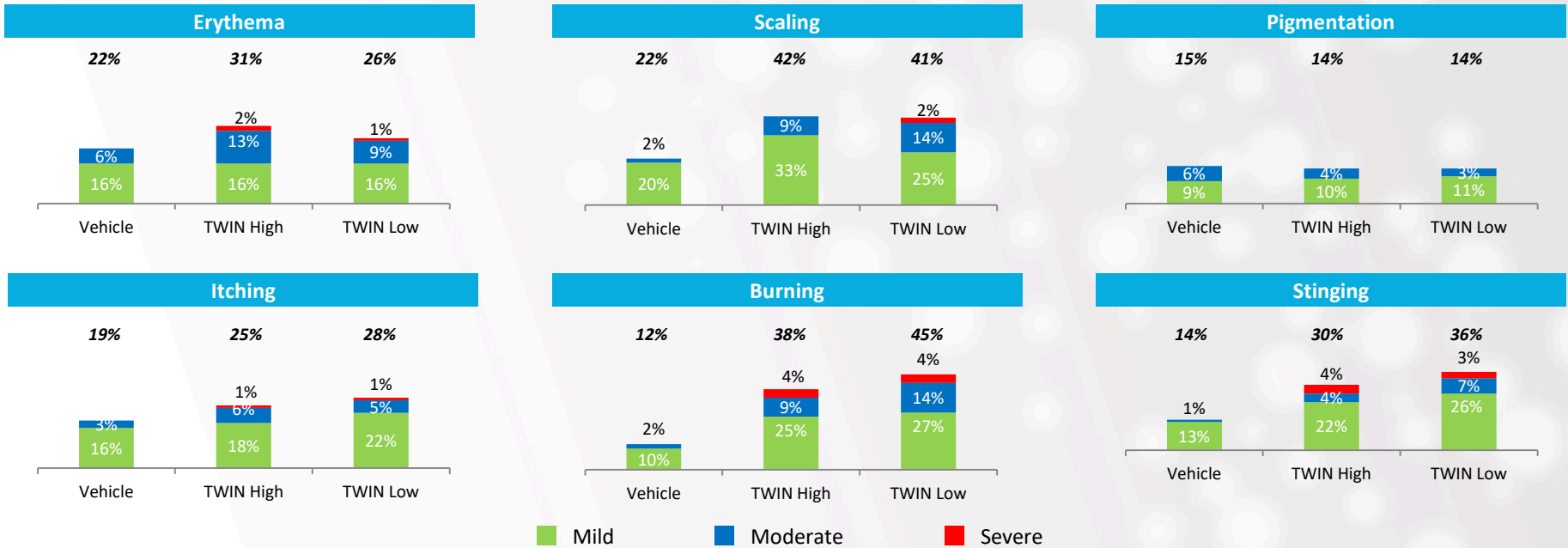
<sup>(†)</sup> Sol-Gel did not conduct a head-to-head comparison trial or study. The results described above are for illustrative purposes only and should not be construed as conclusions to be drawn as if we conducted a head-to-head comparison trial or study



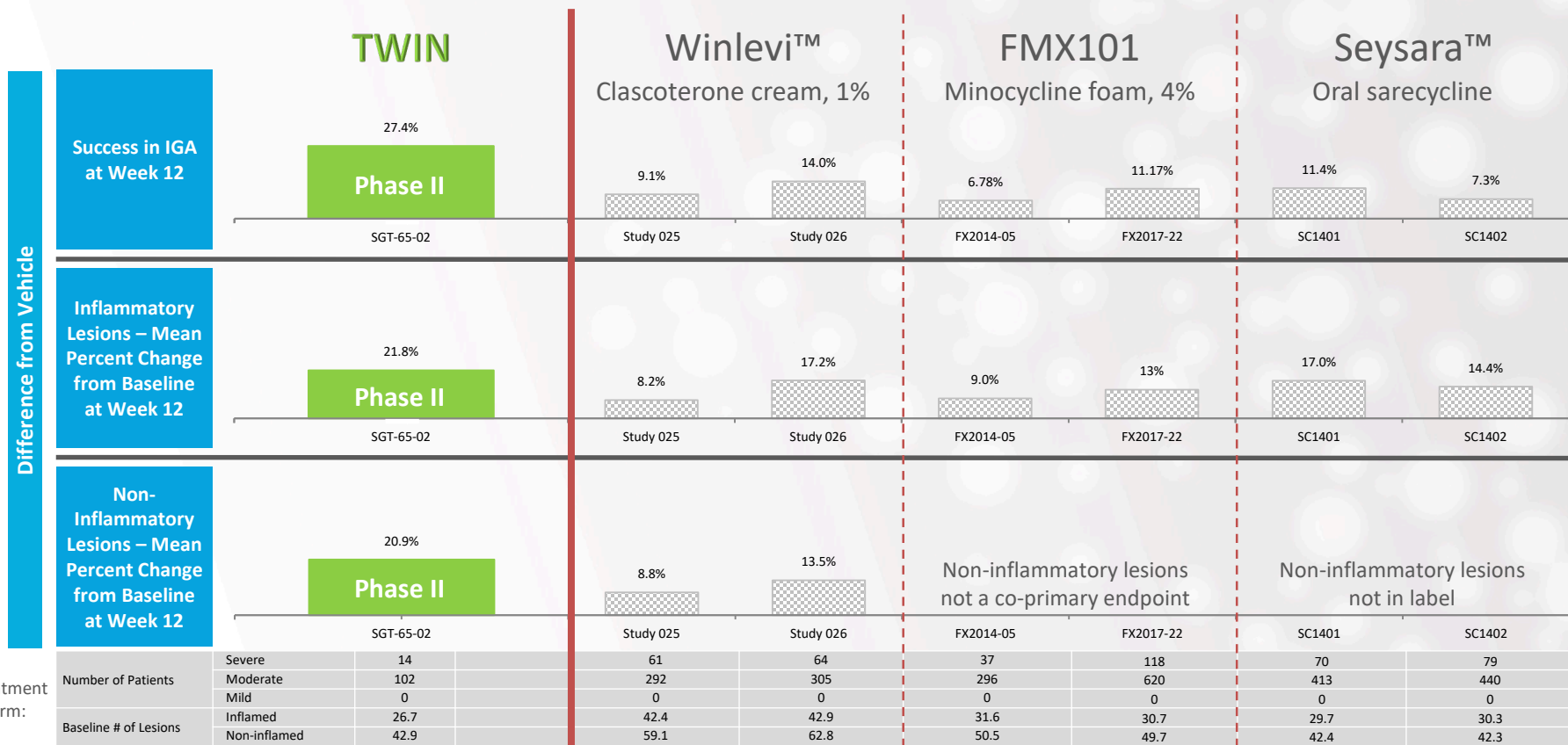
# Phase II Cutaneous Tolerability of TWIN

## Proportion of Subjects with Post-Baseline Worsening of Cutaneous Side Effects (Safety Population)

Max. Post-Baseline > Baseline



# Efficacy Results of Recent Acne Trials<sup>(†)</sup>



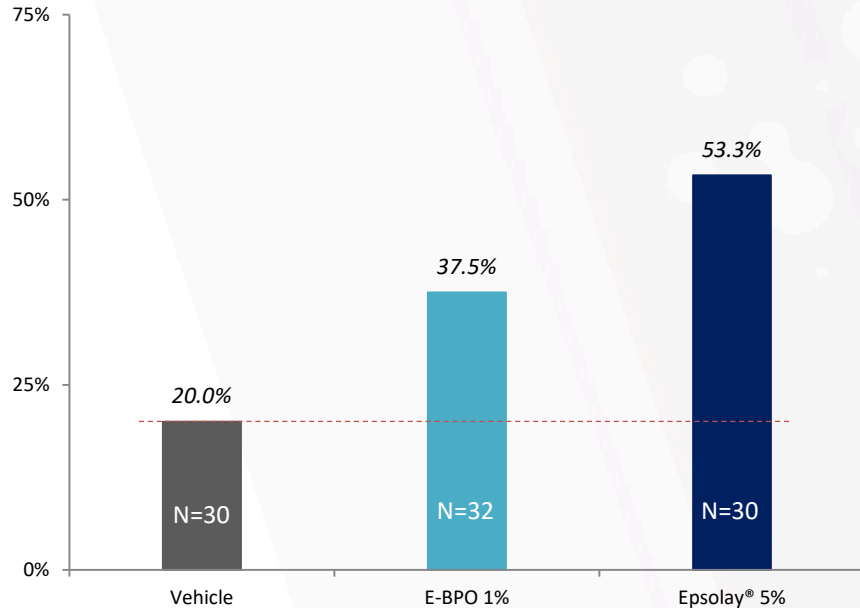
<sup>(†)</sup> Sol-Gel did not conduct a head-to-head comparison trial or study. The results described above are for illustrative purposes only and should not be construed as conclusions to be drawn as if we conducted a head-to-head comparison trial or study

# Positive Epsolay® Phase II Results (ITT)

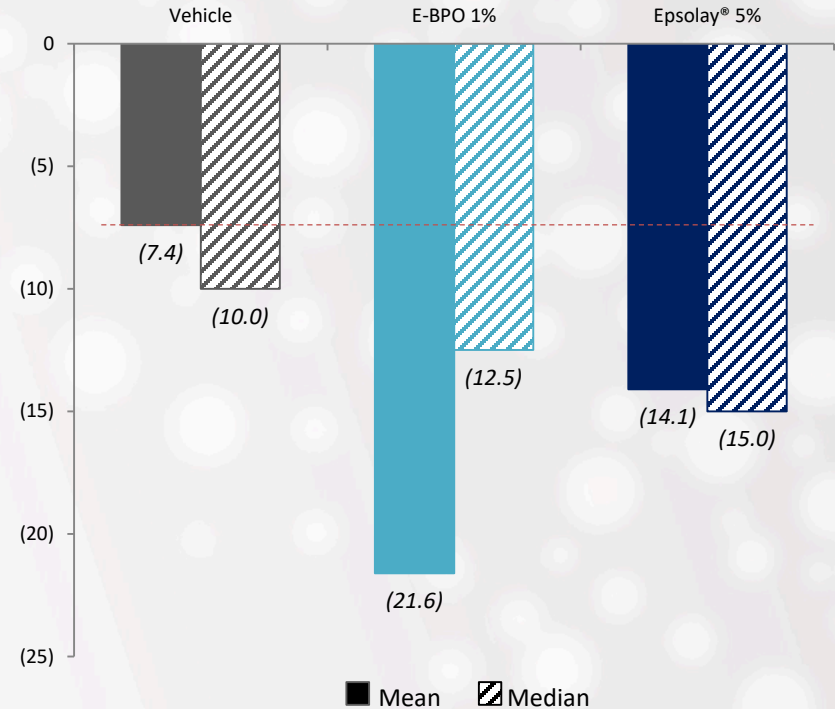
## Success in Dichotomized IGA at Week 12<sup>(†)</sup>

*P-value vs. vehicle*

*0.0013*

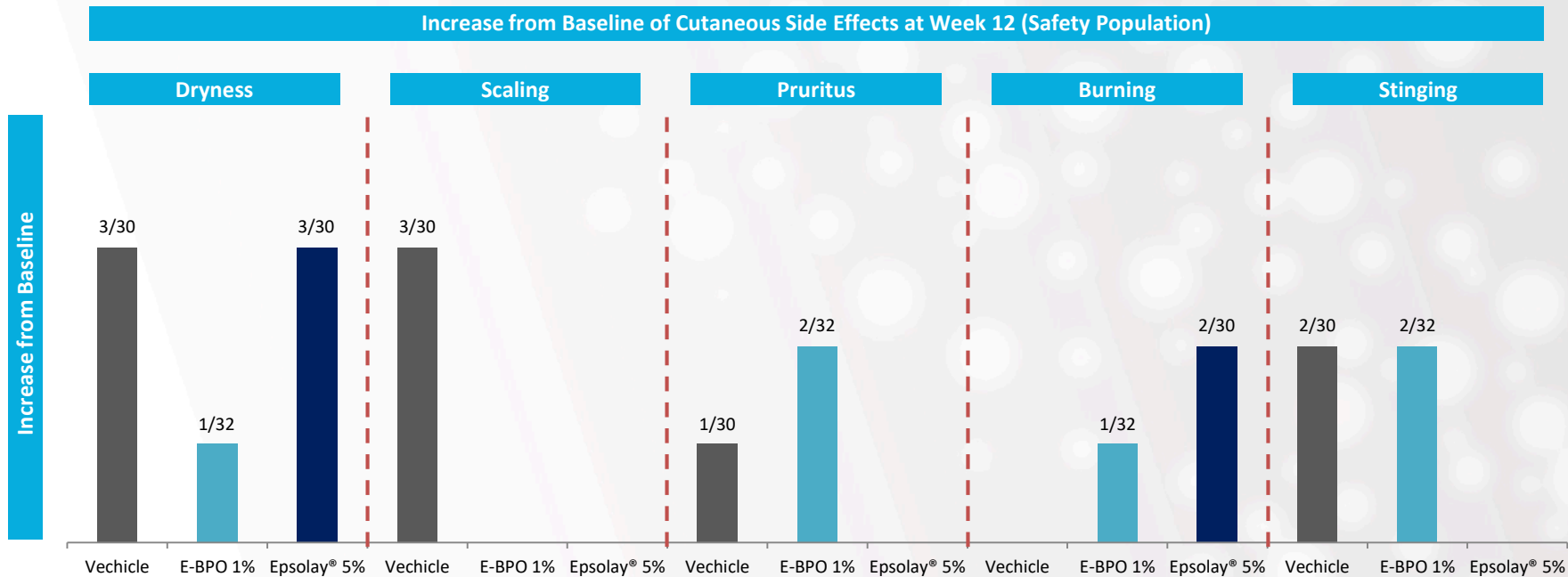


## Inflammatory Lesion Count – Change from Baseline at Week 12



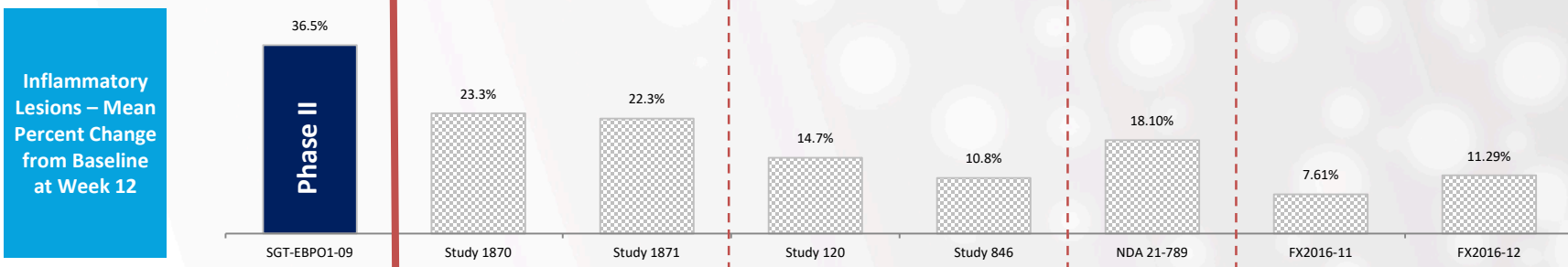
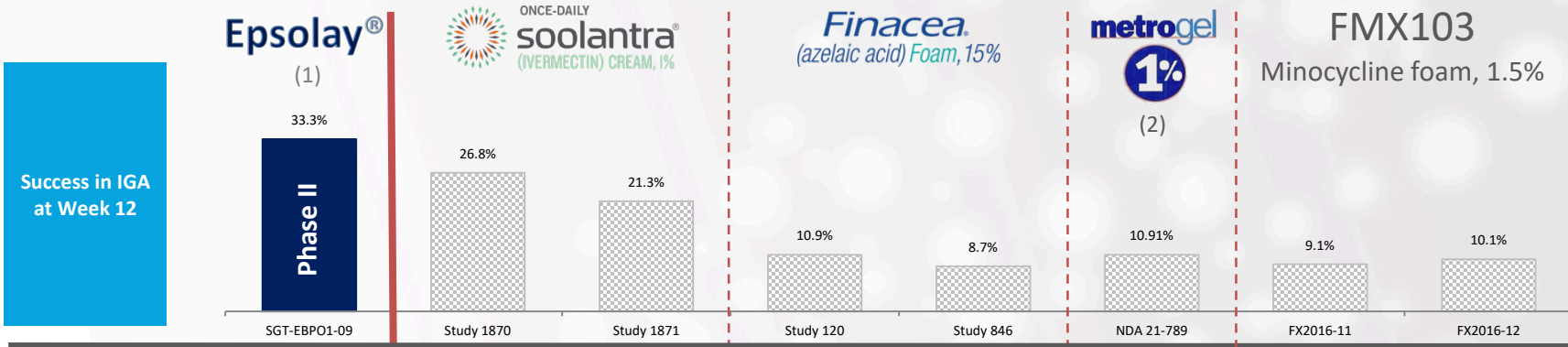
<sup>(†)</sup> The FDA required a modification to our definition of “clear” on the IGA scale such that the category of “clear” represented the absence of the disease. Out of the 11 subjects that were defined as “mild” at baseline, there was only one subject that was treated with Epsolay® 5% and reached “clear” at the end of the trial

# Phase II Cutaneous Tolerability of Epsolay<sup>®</sup>



# Papulopustular Rosacea Trials Results<sup>(†)</sup> (ITT)

Difference from Vehicle



Treatment Arm:	Number of Patients	Severe	5	82	113	26	65	0	51	71
		Moderate	21	369	346	172	418	557	444	443
	Mild	4	0	0	0	0	0	0	0	0
	Baseline # of Inflammatory Lesions		22.9	31.0	33.3	21.6	21.7	18.3	28.5	30.0

(1) "clear" definition: "no inflammatory lesions present with no or very mild erythema immediately localized to and around where inflammatory lesions were present"  
 (2) 10-week study

<sup>(†)</sup> Sol-Gel did not conduct a head-to-head comparison trial or study. The results described above are for illustrative purposes only and should not be construed as conclusions to be drawn as if we conducted a head-to-head comparison trial or study

# Highly-Powered Phase III Trials and Mitigated Risks

## Epsolay®

- Each pivotal trial is planned to enroll 350 subjects in a 2:1 ratio, with a power > 99%
- Long-term safety study (LTSS) was initiated in September 2018
- No pediatric and no Phase I clinical trials are required to support our future marketing application
- Subject to favorable results from our Phase III clinical program, we plan to submit an NDA in 2020

## TWIN

- Only TWIN and vehicle are required for the pivotal trials, as the requirements of the combination rule act were satisfied in our Phase II trial
- Each pivotal trial is planned to enroll 420 subjects in a 2:1 ratio, with a power of 99%
- No LTSS is required to support our future marketing application, as long as we demonstrate that the systemic exposure of our product is comparable to our reference-listed drug (RLD)
- No pediatric clinical studies are required to support our future marketing application
- Subject to favorable results from our Phase III clinical program, we plan to submit an NDA in 2020

# Our Generic Pipeline

## Multiple Collaborations

- A portfolio of generic product candidates with favorable commercial agreements that supplement our branded pipeline
- Seven collaborations with Perrigo and one with Douglas Pharmaceuticals with 50/50 gross profit sharing

## 1<sup>st</sup> Fruitions

- In January 2018, Perrigo received tentative approval from the FDA for ivermectin cream, 1%, developed in collaboration with Sol-Gel. Perrigo was second to file and, as of today, there is no public disclosure of a third filer to the FDA. Sales of RLD reached \$175 million in 2018<sup>(†)</sup>, and are expected to exceed \$200 million annually by 2020
- In February 2019, Perrigo received approval from the FDA and launched the sale of acyclovir cream, 5%, developed in collaboration with Sol-Gel. As of today, there is no public disclosure of another filer to the FDA. The sales of the RLD were ~\$92 million in 2018<sup>(†)</sup>

## Recent Developments

- Bioequivalence (BE) study results for 5-fluorouracil cream, 5%, expected in 2019



# Financial Profile



- Gross proceeds of \$86.3 million raised in IPO of 7,187,500 ordinary shares on February 5, 2018
- 18,949,968 shares outstanding as of March 31, 2019
- \$6.3 million revenue from acyclovir cream in Q1/2019
- \$54.4 million in cash and investments as of the end of Q1/2019
- Cash runway expected to be sufficient to fund Phase III clinical programs for TWIN and Epsolay®, a bioequivalence study, and our activities until the end of Q2/2020

# Our Upcoming Milestones



# Recent Milestones and Next Steps

2017

- Reported positive results from TWIN Phase II trial in acne vulgaris
- Had an EoPll meeting with the FDA about Epsolay®
- Submitted a Paragraph IV ANDA, for ivermectin cream, 1% (sponsored by Perrigo)

2018

- Obtained tentative ANDA approval for ivermectin cream (sponsored by Perrigo)
- Had an EoPll meeting with the FDA about TWIN and addressed the combination rule act
- Initiated Epsolay® Phase III program in papulopustular rosacea
- Initiated LTSS for Epsolay®
- Initiated TWIN Phase III program in acne vulgaris
- Initiated a bioequivalence study for 5-fluorouracil cream, 5% in actinic keratosis
- Hired U.S. commercialization leader for the launches of TWIN and Epsolay®

2019

- Obtained ANDA approval for acyclovir cream (sponsored by Perrigo)
- Launched acyclovir cream (by Perrigo)
- Plans to report Phase III results for Epsolay® in papulopustular rosacea
- Plans to report Phase III results for TWIN in acne vulgaris
- Plans to report BE study results for 5-fluorouracil cream, 5%



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